

MEDICAL LABORATORY BOARD MINUTES

Date: July 14, 2005

Time: 9:00 a.m., CDT

Location: Cumberland Room
Ground Floor, Cordell Hull Building
425 Fifth Avenue North
Nashville, TN 37247

Members Present: Dennis Carter, MD
Edward McDonald, MD
Thomasa Cooper, Medical Technologist
Norman Crowe, Independent Laboratory Manager/Representative
Yvonne Davis, Medical Technologist
Martha Duncan, Medical Technologist
Linda Lahr, Medical Technologist
Alison McDonald-Spakes, Cytotechnologist

Members Absent: Kelly S. Terry, MT Chairman
Jere Ferguson, MD, Vice-Chairman
Delores Voigt, MT Hospital Administrator

Staff Present: Lynda S. England, Medical Technologist, Director
Cheryl H. Thacker, Medical Technologist, Consultant
Robbie Bell, Director-Health Related Boards, Ex-Officio Board

Member

Jerry Kosten, Rules Manager
Robert Kraemer, Jr., Advisory Attorney
Julia Daniels, Medical Technologist Consultant/ Surveyor
East Tennessee Regional Office
Onezean Otey, Jr., Medical Technologist Consultant/Surveyor,
East Tennessee Regional Office
Sandra S. Bogard, Medical Technologist Consultant/Surveyor,
Middle Tennessee Regional Office
Irmgard Brown, Medical Technologist Consultant/Surveyor,
Middle Tennessee Regional Office
Mary Hamblen, Medical Technologist Consultant/Surveyor
West Tennessee Regional Office
Karon Daniels, Medical Technologist Consultant/ Surveyor,
West Tennessee Regional Office

Staff Absent:

Quorum: A sufficient number of board members were present to constitute a quorum.

Presiding Officer: The meeting was called to order by the Personnel and Education Chairman, Linda Lahr at 9:14 a.m. Board Members introduced themselves to the audience. Chairman Terry was unable to attend this meeting. Dr. Ferguson, vice-chair was unable to attend this meeting.

Recognition & Welcome: Ms. Lahr welcomed the guests and visitors to the board meeting.

Board Member Resignation: Ms. Lahr read the written resignation of Monya Pryor, Citizen Representative, to the members.

Board Minutes: A motion to approve the April 14, 2005 board minutes was made by Dr. McDonald.
Second: Ms. McDonald-Spakes
Approved.

A motion to approve the Committee minutes from the April 13, 2005 meeting was made by Dr. McDonald
Second: Ms. Duncan
Approved.

Board Report-Personnel & Education Committee:

Linda Lahr, MT
Committee Chair

Ms. Lahr presented report of the actions of the Personnel & Education Committee meeting held on July 13, 2005.
Motion to accept this report: Dr. McDonald
Second: Ms. Duncan.
Approved.

Petition for Declaratory Order:

Shelby County Health Care Corporation d/b/a/The Regional Medical Center Memphis seeking dismissal of all claims against two (2) of their employees.

After discussion, the board members denied this Petition for a Declaratory Order on a motion by Dr. McDonald. This denial was based on the recommendation of the board's advisory attorney who based this denial on statute and regulation needing no further explanation that could not be part of a contested case hearing.

Second: Mr. Crowe
Approved.

Board Report-Tennessee Professional Peer Assistance Program:

Mike Harkreader, MA, RN
TNPAP State Director

Mr. Harkreader gave two (2) reports to the board:

1-Quarterly Report, March 18, 2005 until May 31, 2005, stated one (1) active participant and two (2) intake participant with 2 referrals from an employer. There has been a total of twenty-eight (28) participants since this agency began advocacy for medical laboratory personnel.

1-Annual Report ,July 1, 2004 until June 30, 2005, stated there were eight (8) referrals with only one (1) signing a monitoring agreement. This agency will report to the Bureau of Investigations those individuals that refused to be monitored by this advocacy group.

Motion to accept this report: Ms. Duncan

Second: Dr. McDonald

Approved.

A copy of Mr. Harkreader's report is on file in the board's administrative office.

Board Report-Rules:

Jerry Kosten-Rules Manager

A. Rules Amendments:

Mr. Kosten reported on a rulemaking hearing held July 8, 2005 concerning the following amendments to:

- 1- Rule 1200-6-1-.20(5)(e)15 Qualifications & Duties of the Medical Laboratory Director.
- 2- Rule 1200-6-1.21 (2)(b) Qualifications & Duties of the Medical Laboratory Supervisor.
- 3- Rule 1200-6-3-.09(8) Quality Control-Control Procedures.
- 4- Rule 1200-6-3-.12(1)(o) Referral of Cultures to the Department of Health.

5- Rule 1200-6-3-.16(1)(c)(5) Alternate Site Testing.

There were no comments during the rulemaking hearing to these proposed rule changes.

A roll call vote was taken with all members present voting aye.

B. Authorize Rulemaking Hearing:

The board authorized a rulemaking hearing to be held September 29, 2005 for:

Amendments to:

1. Rule 1200-6-1-.03 Use of Titles
2. Rule 1200-6-1-.13 Temporary Licenses
3. Rule 1200-6-1-.19 Screening Panels

New Rules

1. Rule 1200-6-2-.08 Advertising
2. Rule 1200-6-3-.20 Advertising

A motion to authorize a rulemaking hearing for Items 1-3 and 1-2 was made by Ms. Davis.

Second: Mr. Crowe.

Approved.

Note: A motion was to withdraw the proposed Rule, 1200-6-1-.13(5), that was adopted on January 14, 2005, to comply with a change that was made during the last legislative session.

Motion: Dr. McDonald

Second: Ms. Cooper

Approved.

Contested Case:

There were no contested cases during this meeting.

Ratifications:

The following items were presented to the Board for ratification per staff, state surveyor or facility request:

- 1) Exemptions for point of care testing procedures (POCT) in a licensed facility (See Attachment 1).
- 2) Initial licenses for Clinical Laboratory Facilities (See Attachment 2).

Board Director's Report/Discussion:

Lynda S. England BS MT(ASCP)

Director

Ms. England reported quarterly administrative office/staff activities to the Board members. This report included administrative office statistics, referrals from this office for TNPAP for peer assistance services and website update information.

Motion: Ms. Duncan.

Second: Dr. Carter.

Report Approved.

The complete report is filed in the administrative office.

Direct More Than Three (3) Labs

Rule 1200-6-3-.13(5) Medical Lab Facilities:

Toni Clinton, Ph.D., currently directs the following ambulatory surgical treatment centers:

- 1) MPL-Midtown Surgery Center, 255 S. Pauline Street, Memphis, TN 38104-3221.
- 2) MPL-Campbell Clinic Surgery Center, 1410 Brierbrook Road, Germantown, TN 38138
- 3) MPL-East Memphis Surgery Center, 80 Humphrey's Blvd., #101, Memphis, TN 38120.

Dr. Clinton requested an exemption from the board to direct the following additional ambulatory surgical treatment centers giving her a total of five (5):

- 4) MPL-Cresthaven, 1004 Cresthaven Road, Memphis, TN 31889.

5) MPL-Germantown, 2100 Exeter Road #101, Germantown, TN 38138.

A motion to exempt from Rule 1200-6-3-.13(5) was made by Dr. McDonald.

Second: Dr. Carter.

Exemption: Approved.

Reinstatement of License: There were no requests for licenses to be reinstated during this meeting.

Reports/Discussion:

Reports:

Regional Consultant/Surveyor – Proficiency Testing (PT) & Complaint Investigations/Licensed Laboratory Facilities

East Tennessee Regional Office- Julia Daniels, Consultant II/Surveyor;
Onezean Otey, Jr., Consultant I/Surveyor

Mr. Otey gave the report:

Unsatisfactory/ Unsuccessful Proficiency Testing:

The East Tennessee Regional Office has conducted zero (0) complaint investigations this quarter.

Complaint Investigations: There was zero (0) investigations during the last quarter of 2005.

Middle Tennessee Regional Office- Sandra S. Bogard, Consultant II/Surveyor; Irmgard A. Brown, Consultant I/Surveyor

Ms. Brown gave the report:

Unacceptable/Unsuccessful Proficiency Testing:

The number of licensed laboratories demonstrating a first occurrence of unsuccessful proficiency testing events (two out of three events) is two (2):

Laboratory #1: Unsuccessful PT for Rh grouping.

Laboratory #2: Unsuccessful PT for hematocrit.

The number of state licensed laboratories with second (2nd) occurrence of unsuccessful proficiency testing events (three out of four/three in a row): zero (0).

Complaint Investigations:

The Middle Tennessee Regional Office has conducted zero (0) complaint investigations during this quarter.

The number of state licensed laboratories with a first occurrence of unsuccessful proficiency testing (two out of three or two in a row): one (1).

West Tennessee Regional Office-Mary J. Hamblen, Consultant II/Surveyor; Karen Daniels, Consultant I/Surveyor

Ms. Daniels gave the report:

Unacceptable/Unsuccessful Proficiency Testing:

The number of state licensed laboratories with second occurrence of unsuccessful proficiency testing (three out of four or three in a row): zero (0).

Complaint Investigations:

There were zero (0) complaint investigations from the West Tennessee Regional Office this quarter.

Motion: Ms. Davis
Second: Ms. Cooper
Report Approved.

Reports/Discussion: There were no scheduled reports or discussions during this segment of the meeting.

Health Related Board's Report/Discussion:

Robbie Bell, Director

Ms. Bell reported the Bureau of Health Licensure and Regulation will be moving to a different location as soon as the building is renovated. This facility will provide a parking area for walk in licensees and also more room for HRB (health related boards). Many projected improvements will be part of this move including a board meeting room wired for laptops. We will have the ability to video stream the board meetings to the public and the meetings may be seen on the internet. There will be an "Extranet" that is secured for board member/state staff to utilize. These improvements should mark a great improvement in current multi-paper board books.

Motion to accept report: Dr. McDonald
Second: Ms. Duncan
Approved.

Office of General Counsel Report:

Robert J. Kraemer, Jr.
Advisory Attorney

Mr. Kraemer led the discussion of the following items:

Screening Tests and Civil Penalties (04-1378) The rulemaking hearing was held on September 23, 2004 and this amendment was adopted by the Board on October 14, 2004. They were signed by the Attorney General and filed with the Secretary of State on May 16, 2005 and become **effective July 30, 2005**.

Continuing Education, Temporary Licensure & Lab Test Orders (04-1554) The rulemaking hearing was held on December 17, 2004 and these amendments were adopted by the Board on January 14, 2005. These amendments were sent to the Attorney General on January 18, 2005 and are still there. Note: The board voted during this meeting to withdraw the promulgated rule for temporary license in favor of new legislation on the matter.

Criminal Background Checks & Screenings (05-1026) The rulemaking hearing was held on March 24, 2005 and these amendments were adopted by the Board on April 14, 2005. They were sent to the Attorney General on April 19, 2005 and they are still there.

Director, Delegation, Reportable Cultures and POC (05-1170) The rulemaking hearing was held on July 8, 2005 and these amendments were adopted by the Board on July 14, 2005.

Litigation:

The Office of General Counsel currently has two (2) open disciplinary cases pertaining to the Medical Laboratory Board.

Topics for Discussion:

Mr. Kraemer discussed the following Public Chapters involving the laboratory arena:

Public Chapter 113-Medical Records-Release from liability.
Public Chapter 118-Medical Records Access.
Public Chapter 172-Chronic Kidney Disease Screening Act.
Public Chapter 467-Advertising and Titles.
Public Chapter 479-Temporary Licenses.

Motion: Ms. Duncan
Second: Ms. Davis
Report Approved.

Bureau of Investigations (BIV) Report:

Ms. England gave this report from information provided by the Bureau of Investigation which included three (3) open complaints in BIV which were carried over from December 2004. There have been zero (0) new complaints filed during this quarter. A report of previous disciplinary actions on licensed personnel was also included in each board book.

Motion: Ms. Davis
Second: Dr. Carter
Report Approved.

Office of Health Licensure & Regulation:

Judy Eads, RN
Assistant Commissioner of Health

Ms. Eads did not make a report at this time.

Financial Report:

Lisa Tittle
Fiscal Officer

A copy of the financial report for the fiscal year 2004-2005 was mailed to each board member earlier in the month. A copy of this report is included in each member's board book and also on file in the administrative office.

Motion: Dr. McDonald
Second: Ms. Cooper
Report Approved.

Waived Testing Procedures:

There were no additions or deletions made to the waive test lists.

Point of Care Task Force:

There was no report made by the task force during this meeting.

Review Eligibility of Medical Laboratory Director:

No requests were presented to the Board during this meeting.

Other Business:

There were several issues discussed as "Factual Situations" that were presented to the board's director:

Factual Situation #1 A physician's assistant buys a physician's practice and laboratory samples are referred to a group practice laboratory to which the physician's assistant/physician preceptor is a group partner. Does that make the physicians group laboratory a referral laboratory.

The board discussed this situation and determined that the physician assistant could not operate without oversight of a physician (Rules 0880-2-.18 and Rules 0880-3-.10) therefore this laboratory receiving specimens from this physician's assistant location will remain a physicians office laboratory.

Factual Situation #2-Designated/board exempted point of care sites are those locations that can provide a quick turn around time for “bedside testing procedures” which defines point of care. To conduct testing outside the scope of these exemptions would be in conflict with Rule 1022-6-3-.16. An alternative would be for the facility to request an additional site.

Factual Situation # 3 A physician group laboratory performs approximately a quarter million tests a year. One or more members of this group have a practice not in Tennessee and submit laboratory samples to this Tennessee POL. After discussion, the board decided to research this scenario with rules and statutes pertaining to medical practice. This item will be put on the agenda for the October meeting.

Factual Situation #4 A blood donor center is performing diagnostic testing for bacterial contamination on platelets infused with materials to extend the shelf life of this blood component. This procedure was implemented according to March 2004 American Association of Blood Bank Standards. The question arises as to the category of this test rather is this still an immunohematology or blood bank procedure or is this procedure a fall under the clinical category of bacteriology. The board decided to put this item on the October agenda after further review of this situation.

Statement of Next Meeting: The next meeting will be held on October 13, 2005 beginning at 9 am, CDT in the Cumberland Room, Ground Floor Cordell Hull Building, 425 Fifth Avenue North, Nashville, TN 37247-1010.

Record of Adjournment: The meeting adjourned at 12:40 pm C.D.T. on a motion properly filed by Ms. Duncan.
Second: Ms. Cooper
Approved.

Linda Lahr, MT
Chairman Personnel & Education Committee

Date

REQUEST FOR EXEMPTION-POINT OF CARE TESTING PROCEDURES

1. Harton Regional Medical Center
1801 North Jackson Street
Tullahoma, TN 37388

Facility Representative: Marla F. Beatty, CHE, MT(ASCP)
Administrative Director of Laboratory Services

This facility request was for Registered Nurses (RN's) and Licensed Practical Nurses (LPN's) to perform and report cardiac markers (CK-MB, myoglobin, troponin-I and BNP) in the Emergency Department utilizing the Biosite Triage® Cardio Profiler instrument and methodologies.

Motion: Dr. McDonald
Second: Ms. Cooper
Approved.

2. Jackson Madison County General Hospital
708 West Forest Avenue
Jackson, TN 38301

Facility Representative: Jerry Barker
Assistant Laboratory Director

This facility request was for Clinical Perfusionists to perform and report acid-base/oxygen parameters, electrolytes and hematocrit utilizing the Radiometer ABL 77 Series instrument and methodology. These tests will be performed in the Anesthesiology Department.

Motion: Dr. McDonald
Second: Ms. Duncan
Approved.

3. Baroness Erlanger Hospital Laboratory
975 East Third Street
Chattanooga, TN 37043-2112

Attachment 1
Medical Laboratory Board
Point of Care Exemption Requests
July 14, 2005

Facility Representative: Mary Hooper, Laboratory Support Services Manager
Caren Lewis, Director of Patient Care

This request was for Respiratory Therapists to perform and report sodium, potassium, chloride, CO₂, ionized calcium, hematocrit, blood urea nitrogen (BUN), creatinine and lactate utilizing the i-STAT instrument and methodologies campus wide.

Motion: Dr. McDonald
Second: Dr. Carter
Approved.

4. Wellmont Holston Valley Medical Center
PO Box 238
Kingsport, TN 37662

Facility Representative: Richard Doyle, Laboratory Services

This facility made the following exemption requests:

- 1- Permit Nurses (RN's & LPN's) and Respiratory Therapists to perform and report troponin, myoglobin, CK-MB and BNP in the Emergency Room utilizing the Biosite Triage Instrument.
- 2- Permit Nurses (RN's & LPN's) to perform and report activated clotting time (ACT) in the Post Anesthesia Care Unit (PACU) utilizing the Hemochron instrument.
- 3- Permit Nurses (RN's & LPN's), Respiratory Therapists and Certified Phlebotomists to perform and report urinalysis procedures in the Emergency Room. The instrument that will be utilized is the Bayer Clinitek Status Analyzer.

Motion: Ms. Duncan
Second: Mr. Crowe
Approved.

Ms. Lahr recused herself from the discussion and vote.

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Point of Care Exemption Requests
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5. Wellmont Bristol Regional Medical Center
1 Medical Park Blvd.
Bristol, TN 37620

Facility Representative: Gail Price, MT(ASCP)
Director of Laboratory Services

This facility made the following exemption requests:

- 1- Permit Registered Nurses, Licensed Practical Nurses and Respiratory Therapists to perform and report troponin, myoglobin, CK-MB and BNP in the Emergency Room. The instrument used in these procedures is the Biosite® Triage instrument.
- 2- Permit Perfusionists to perform and report sodium, potassium, glucose, ionized calcium, lactate, hematocrit, pH, PCO₂ and pO₂ on the GEM 3000 instrument in the CVOR.
- 3- Permit Registered Nurses, Licensed Practical Nurses and Respiratory Therapists to perform and report sodium, potassium, chloride, ionized calcium, glucose and hematocrit on the Radiometer ABL800 FLEX instrument in the Emergency Department.
- 4- Permits Registered Nurses, Licensed Practical Nurses, Respiratory Therapists and Certified Phlebotomists to perform and report urinalysis procedures in the Emergence Department utilizing the Bayer Clinitek Status.

Motion: Ms. Davis
Second: Dr. Carter
Approved.

Ms. Lahr recused herself from this discussion and vote.

INITIAL FACILITY LICENSES: REGIONAL SURVEYOR RECOMMENDATION:

Blood Assurance, Inc.

Tullahoma Donor Center
1500 North Jackson Street
Suite 200
Tullahoma, TN 37388

Medical Laboratory Director: Bruce A. Elrod, M.D.

ABP

Anatomic & Clinical Pathology

Specialties: Spun Hematocrit/Blood Donor Center

Surveyor: Sandra S. Bogard, Consultant II
Middle TN Regional Office

Tennessee Blood Services, Inc.

807 Poplar Avenue
Memphis, TN 38105

Medical Laboratory Director: Jerald E. Mullersman, M.D.

ABP

Anatomic & Clinical Pathology

Specialties: General Immunology and Syphilis Serology

Surveyor: Karon Daniels, Consultant I
West TN Regional Office

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Attachment 2
Initial Facility Licenses
July 14, 2005

Lab-One Clarksville
1820 Memorial Drive Suite 203
Clarksville, TN 37043

Medical Laboratory Director: Pushpendra Kumar Jain, M.D.
General Practice

Specialties: Collection Station
Surveyor: Sandra S. Bogard, Consultant II
Middle TN Regional Office

Lab One-Cookeville
225 North Willow Avenue Suite 2
Cookeville, TN 38501

Medical Laboratory Director: Pushpendra Kumar Jain, M.D.
General Practice

Specialties: Collection Station
Surveyor: Sandra S. Bogard, Consultant II
Middle TN Regional Office

Lab One-Tullahoma
1330 Cedar Lane
Tullahoma, TN 37388

Medical Laboratory Director: Raymond L. Capps, M.D.
Urology

Specialty: Collection Station
Surveyor: Irmgard A. Brown, Consultant I
Middle TN Regional Office

Motion to approve all initial licenses: Dr. McDonald
Second: Ms. Duncan
Licenses Approved.

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